



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 5/15/2017

Subject: Efficacy Review for Valhalla, EPA Reg. No. 83614-R
(DP Barcode: 437544, E-Submission: N/A)

From: Samantha Collins
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Eric Miederhoff, Team 31 / Tara Flint
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Byotrol, Inc.
3740 Boiling Springs Hwy. #119
Boiling Springs, SC 29316

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
1-Decanaminium, N-decyl-N, N-dimethyl-,chloride	0.324%
Alkyl dimethyl benzyl ammonium chloride (67%C12, 25%C14, 7%C16,1% C18)	0.215%
Poly (hexamethylenebiguanide) hydrochloride	0.539%
<u>Other Ingredients</u>	98.922%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): RTU Liquid Spray

Submission type: New product registration

Currently registered efficacy claim(s): N/A

Requested action(s): Review submitted product efficacy data for disinfection claims against bacteria, viruses and fungi. Data also submitted for mold/mildew fungistatic claims, non-food contact sanitization claims and residual self-sanitizing claims.

Documents considered in this review:

- Letter from applicant to EPA dated December 16, 2016
- Data Matrix (EPA Form 8570-35)
- 15 efficacy studies (MRID 50138512-50138526)
- Proposed label dated 12/19/2016 (pin punch)
- Confidential Statement of Formula (EPA Form 8570-4) dated 12/16/2016.

II PROPOSED DIRECTIONS FOR USE

“To Clean [and] [Deodorize]: Wet the surface with the spray and wipe clean.

To Sanitize [Non-food Contact Sanitizer]: For hard, non-porous, [non-food contact] surfaces, spray [this product] [6-8 inches from] [on] surface until thoroughly wet. Let stand for [10 seconds]. Wipe dry. [No rinsing required.] Remove heavy soil prior to sanitization.

For General [Broad Spectrum] [Bacterial Spectrum] [Bacterial] Disinfection: Spray [this product] [6-8 inches from] hard, non-porous surface until thoroughly wet. Let stand 2 minutes [for bacteria, 1 minute for enveloped viruses and 10 minutes for fungi]. Wipe dry. [No rinsing required.] Preclean if heavy soil is present. [To disinfect fungi, let stand for 10 minutes. To disinfect, [enveloped viruses] [coronavirus, Influenza A H1N1, and RSV], let stand for 1 minute. To disinfect Rotavirus, let stand 2mins. To disinfect Norovirus, let stand 5 mins.]

For Hospital Disinfection of Bacteria and Viruses: Spray [this product] [6-8 inches from] hard, non-porous surfaces until thoroughly wet. Let stand 5 minutes. Wipe dry. [No rinsing required.] Preclean if heavy soil is present. To disinfect fungi, let stand for 10 minutes.”

III STUDY SUMMARIES

1.	MRID	50138512	Study Completion Date:		06/29/16	
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Salmonella enterica</i> (ATCC 10708) and <i>Staphylococcus aureus</i> (ATCC 6538)				
Test Method		AOAC Germicidal Spray Method				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	RSH018/38, RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Glass slides, 60 per batch per organism				
Test conditions		Contact time	1min/2min	Temp	20-21°C	RH 42-50%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20423				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Testing on 3/15/16 resulted in failing efficacy results against <i>Staphylococcus aureus</i> (ATCC 6538) at a one-minute contact time. Protocol was amended per registrants request and <i>Staphylococcus aureus</i> was retested on 4/18/16 with a two-minute contact time, concluding with acceptable results.				

2.	MRID	50138513	Study Completion Date:		04/22/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> (ATCC 15442)				
Test Method		AOAC Germicidal Spray Method				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	RSH018/38, RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Glass slides, 60 per batch				
Test conditions		Contact time	4.5 min	Temp	20°C	RH 46%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20424				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

3.	MRID	50138514	Study Completion Date:		09/02/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> O157:H7 (ATCC 43888)				
Test Method		AOAC Germicidal Spray Method				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	2 min	Temp	21°C	RH 56%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21320				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

4.	MRID	50138515	Study Completion Date:		09/09/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Listeria monocytogenes</i> (ATCC 7644)				
Test Method		AOAC Germicidal Spray Method				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	2 min	Temp	21.3°C	RH 46%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21322				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

5.	MRID	50138516	Study Completion Date:		09/09/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Streptococcus pyogenes</i> (ATCC 12384)				
Test Method		AOAC Germicidal Spray Method				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	2 min	Temp	21°C	RH 50%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21323				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

6.	MRID	50138517	Study Completion Date:		02/10/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		2009-H1N1 Influenza A virus (novel H1N1) StainA/Mexico/4108/2009, CDC #2009712192				
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH016/15, RSH016/9				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Petri dish, 1 carrier/surface per batch				
Test conditions		Contact time	1 min	Temp	20°C	RH
Testing Lab, Lab Study ID		Accuratus Lab Services, A17746				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

7.	MRID	50138518	Study Completion Date:		02/23/16
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Respiratory syncytial virus (ATCC VR-26, Strain Long)</i>			
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces			
Application Method		RTU Liquid spray			
Test Substance Preparation	Name/ID	Valhalla			
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH016/15, RSH016/9			
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A			
Soil load		5% fetal bovine			
Carrier type, # per lot		Petri dish, 1 carrier/surface per batch			
Test conditions		Contact time	1 min	Temp	20°C RH
Testing Lab, Lab Study ID		Accuratus Lab Services, A17747			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Initial assay performed on 1/14/15 was invalid due to inability to recover at least 3 log ₁₀ of infectivity from the dried virus control beyond the cytotoxic level of the test substance as required, repeated with valid results on 1/15/15.			

8.	MRID	50138519	Study Completion Date:		06/05/15
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Human Coronavirus (ATCC VR-740, Strain 229E)</i>			
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces			
Application Method		RTU Liquid spray			
Test Substance Preparation	Name/ID	Valhalla			
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH016/15, RSH016/9			
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A			
Soil load		5% fetal bovine			
Carrier type, # per lot		Petri dish, 2 lots per strain			
Test conditions		Contact time	1 min	Temp	20°C RH
Testing Lab, Lab Study ID		Accuratus Lab Services, A17745			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Initial assay performed on 1/14/15 was invalid due to inability to recover at least 3 log ₁₀ of infectivity from the dried virus control beyond the cytotoxic level of the test substance as required, repeated with valid results on 1/27/15.			

9.	MRID	50138520	Study Completion Date:		08/18/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Rotavirus (ATCC VR-2018, Strain WA)</i>				
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Petri dish, 2 lots per strain				
Test conditions		Contact time	2 min	Temp	20°C	RH
Testing Lab, Lab Study ID		Accuratus Lab Services, A21316				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

10.	MRID	50138521	Study Completion Date:		10/05/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Feline Calicivirus as a surrogate virus for Norovirus</i>				
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Petri dish, 2 lots per strain				
Test conditions		Contact time	5 min	Temp	20°C	RH
Testing Lab, Lab Study ID		Accuratus Lab Services, A21268				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Initial assay performed on 7/20/16 was invalid due to inability to recover at least 3 log ₁₀ of infectivity from the dried virus control beyond the cytotoxic level of the test substance as required, repeated with invalid results on 08/18/16. Test repeated again on 08/31/16 to recover at least 4 log ₁₀ of infectivity from both dried virus control replicates and to demonstrate 3 log ₁₀ of infectivity from the dried virus control beyond the cytotoxic level of the test substance as required. Valid results obtained on 8/31/16.				

11.	MRID	50138522	Study Completion Date:		09/07/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Trichophyton mentagrophytes</i> (ATCC 19533)				
Test Method		Fungicidal Germicidal Spray Method				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	9.5 min	Temp	19.3°C	RH 66%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21321				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

12.	MRID	50138523	Study Completion Date:		02/01/16	
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Staphylococcus aureus</i> (ATCC 6538)				
Test Method		Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces (with exposure and wear activity)				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	RSH018/38, RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine (Heat inactivated)				
Carrier type, # per lot		Glass slides, 4 test carriers per batch and 4 control carriers				
Test conditions		Contact time	4.5 min	Temp	21°C	RH 50%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19575				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

13.	MRID	50138524	Study Completion Date:		02/01/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Enterobacter aerogenes</i> (ATCC 13048)				
Test Method		Residual self-sanitizing Activity of Dried Chemical Residues on Hard Nonpourous Surfaces (with exposure and wear activity)				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	RSH018/38, RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine (Heat inactivated)				
Carrier type, # per lot		Glass slides, 4 test carriers per batch and 4 control carriers				
Test conditions		Contact time	4 min 45 sec	Temp	20°C	RH 50%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19655				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

14.	MRID	50138525	Study Completion Date:		10/05/16	
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Enterobacter aerogenes</i> (ATCC 13048), <i>Staphylococcus aureus</i> (ATCC 6538)				
Test Method		Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH018/38, RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Glass slides, 3 per batch				
Test conditions		Contact time	10 sec	Temp	20-21°C	RH 27-53%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20703				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Multiple trials were deemed invalid on dates 4/20/16, 4/29/16 and 5/26/16 due to neutralization control failures. Protocol amendments were made on the neutralizer concentration used and hold times per sponsors request. Valid results were produced on 6/15/16.				

15.	MRID	50138526	Study Completion Date:		08/31/16	
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Aspergillus niger</i> (ATCC 6275)				
Test Method		Hard Surface Mildew-Fungistatic Test				
Application Method		RTU Liquid spray				
Test Substance Preparation	Name/ID	Valhalla				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	RSH018/39, RSH018/40				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% fetal bovine				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	7 days	Temp	25-30°C	RH 95%
Testing Lab, Lab Study ID		Accuratus Lab Services, A21306				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		None				

IV STUDY RESULTS

1. Disinfection – Bactericidal Efficacy

Contact time	MRID No.	Organism	No. Carriers Exhibiting Growth/Total Carriers			Carrier Population (Log ₁₀ CFU/Carrier)
			Batch RSH018/38	Batch RSH018/39	Batch #RSH018/40	
5% soil load, RTU						
1 min	50138512	<i>Staphylococcus aureus</i> (ATCC 6538) 3/15/16	6/60*	4/60*	2/60*	5.58
1 min		<i>Salmonella enterica</i> (ATCC 10708) 3/15/16	0/60	0/60	0/60	4.86
2 min		<i>Staphylococcus aureus</i> (ATCC 6538) 4/18/16	0/60	0/60	1/60	5.71
4.5 min	50138513	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/60	0/60	0/60	5.99
2 min	50138514	<i>Escherichia coli</i> O157:H7 (ATCC 43888)	--	0/10	0/10	5.03
2 min	50138515	<i>Listeria monocytogenes</i> (ATCC 7644)	--	0/10	0/10	6.35
2 min	50138516	<i>Streptococcus pyogenes</i> (ATCC 12384)	--	0/10	0/10	5.88

*Invalid result

2. Hard Non-Porous Surface Virucidal Disinfectant:

Contact time	MRID No.	organism	Results		
				Batch # RSH016/15	Batch # RSH016/9
5% soil load, RTU					
1 min	50138517	2009-H1N1 Influenza A virus (novel H1N1) StainA/Mexico /4108/2009, CDC #2009712192	Description	Avg. Rep. 1-5	Avg. Rep. 1-5
			10 ⁻¹ to 10 ⁻⁷ dilutions	Complete Inactivation	Complete Inactivation
			TCID ₅₀ /100μL	≤10 ^{2.50}	≤10 ^{2.50}
			Log ₁₀ Reduction	≥3.50	≥3.50
			Average Dried Virus Control (TCID ₅₀ /100μL)	6.00 log ₁₀	
1 min	50138518	Respiratory syncytial virus (ATCC VR-26, Strain Long)	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete Inactivation	Complete Inactivation
			TCID ₅₀ /100μL	≤10 ^{1.50}	≤10 ^{1.50}
			Log ₁₀ Reduction	≥3.50	≥3.50
			Average Dried Virus Control (TCID ₅₀ /100μL)	5.00 log ₁₀	
			1 min	50138519	Human Coronavirus (ATCC VR-740, Strain 229E)
TCID ₅₀ /100μL	≤10 ^{1.50}	≤10 ^{1.50}			
Log ₁₀ Reduction	≥4.25	≥4.25			
Average Dried Virus Control (TCID ₅₀ /100μL)	5.75 log ₁₀				

Contact time	MRID No.	organism	Results		
				Batch # RSH018/39	Batch # RSH018/40
5% soil load, RTU					
2 min	50138520	Rotavirus (ATCC VR-2018, Strain WA)	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete Inactivation	Complete Inactivation
			TCID ₅₀ /100μL	≤10 ^{2.50}	≤10 ^{2.50}
			Log ₁₀ Reduction	≥3.50	≥3.50
			Average Dried Virus Control (TCID ₅₀ /100μL)	6.00 log ₁₀	
5 min	50138521	Feline Calicivirus as a surrogate virus for Norovirus	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete Inactivation	Complete Inactivation
			TCID ₅₀ /100μL	≤10 ^{1.50}	≤10 ^{1.50}
			Log ₁₀ Reduction	≥3.21	≥3.21
			Average Dried Virus Control (TCID ₅₀ /100μL)	Rep. #1: 4.50 log ₁₀	
				Rep. #2: 5.00 log ₁₀	

3. Disinfection – Fungicidal Efficacy

Contact time	MRID	Organism	No. Exhibiting Growth/Total No. Tested		Average log ₁₀ CFU/Carrier
			Batch RSH018/39	Batch RSH018/40	
5% soil load, RTU					
9.5 min	50138522	Trichophyton mentagrophytes (ATCC 9533)	0/10	0/10	4.67

4. Residual self-sanitizing Activity of Dried Chemical Residues on Hard Nonpourous Surfaces (with exposure and wear activity):

Contact Time	MRID No.	Organism	Results			Carrier Population CFU/Carrier (Avg. Log ₁₀)
			Batch#	CFU/Carrier (Average log ₁₀)	Percent Reduction	
5% soil load, RTU						
4.5 min	50138523	<i>Staphylococcus aureus</i> (ATCC 6538)	RSH018/38	<3.02 x 10 ¹ (<1.48)	>99.9	4.17 x 10 ⁵ (5.62)
			RSH018/39	<3.02 x 10 ¹ (<1.48)	>99.9	
			RSH018/40	<6.46 x 10 ¹ (<1.81)	>99.9	
4 minutes 45 seconds	50138524	<i>Enterobacter aerogenes</i> (ATCC 13048)	RSH018/38	<3.02 x 10 ¹ (<1.48)	>99.9	1.45 x 10 ⁶ (6.16)
			RSH018/39	<3.02 x 10 ¹ (<1.48)	>99.9	
			RSH018/40	<3.02 x 10 ¹ (<1.48)	>99.9	

5. Hard, Non-Porous, Non-Food Contact Surface Sanitizer:

Contact Time	MRID No.	Organism	Results			Carrier Population CFU/Carrier (Avg. Log ₁₀)
			Batch#	CFU/Carrier (Average log ₁₀)	Percent Reduction	
10 seconds	50138525	<i>Staphylococcus aureus</i> (ATCC 6538)	RSH018/38 4/29/16	<2.00 x 10 ² (<2.30)	>99.9	1.91 x 10 ⁶ (6.28)
			RSH018/39 5/26/16	<2.00 x 10 ² (<2.30)	>99.9	2.63 x 10 ⁶ (6.42)
			RSH018/40 6/15/16	<2.00 x 10 ¹ (<1.30)	>99.9	1.58 x 10 ⁶ (6.20)
		<i>Enterobacter aerogenes</i> (ATCC 13048)	RSH018/38 4/29/16	<2.29 x 10 ¹ (<1.36)	>99.9	6.46 x 10 ⁶ (6.81)
			RSH018/39 5/29/16	<2.00 x 10 ¹ (<1.30)	>99.9	
			RSH018/40 4/29/16	<2.00 x 10 ¹ (<1.30)	>99.9	

6. Hard Surface Mildew-Fungistatic:

Contact Time	MRID No.	Organism	Visual Evaluation		Magnified Evaluation		*Untreated Carrier Results (Pass/Fail)
			Batch # RSH018/39	Batch # RSH018/40	Batch # RSH018/39	Batch # RSH018/40	
Day 7	50138526	<i>Aspergillus niger</i> (ATCC 6275)	0% coverage on 10 carriers	0% coverage on 10 carriers	No growth on 10 carriers	No growth on 10 carriers	Pass on 10 carriers

*To be considered passing, each control carrier must demonstrate $\geq 50\%$ coverage at Day 7.

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50138512	Disinfectant, bactericidal	Hard, non-porous surfaces	RTU	1 minute	5%	N/A	• <i>Salmonella enterica</i> (ATCC 10708)	Yes
50138513				4.5 minutes			• <i>Pseudomonas aeruginosa</i> (ATCC 15442)	
50138512				2 minutes			• <i>Staphylococcus aureus</i> (ATCC 6538) • <i>Escherichia coli</i> O157:H7 (ATCC 43888) • <i>Listeria monocytogenes</i> (ATCC 7644) • <i>Streptococcus pyogenes</i> (ATCC 12384)	
50138514								
50138515								
50138516								
50138517	Disinfectant, Virucidal	Hard, non-porous surfaces	RTU	1 minute	5%	N/A	• 2009-H1N1 Influenza A virus (novel H1N1) StainA/Mexico/4108/2009, CDC #2009712192 • Respiratory syncytial virus (ATCC VR-26, Strain Long) • Human Coronavirus (ATCC VR-740, Strain 229E)	Yes
50138518								
50138519								

50138520				2 minutes			• <i>Rotavirus (ATCC VR-2018, Strain WA)</i>	
50138521				5 minutes			• <i>Feline Calicivirus as a surrogate virus for Norovirus</i>	
50138522	Disinfectant, fungicidal	Hard, non-porous surfaces	RTU	9.5 minutes	5%	N/A	• <i>Trichophyton mentagrophytes</i> (ATCC 9533)	Yes
50138523 50138524	Residual Self-Sanitizing	Hard, non-porous surfaces	RTU	4.5 minutes	5%	N/A	• <i>Staphylococcus aureus</i> (ATCC 6538)	Yes
				4 minutes 45 seconds			• <i>Enterobacter aerogenes</i> (ATCC 13048)	
50138525	Sanitizer	Hard, non-porous surfaces	RTU	10 seconds	5%	N/A	• <i>Enterobacter aerogenes</i> (ATCC 13048) • <i>Staphylococcus aureus</i> (ATCC 6538)	Yes
50138526	Mildew-Fungistatic	Hard, non-porous surfaces	RTU	7 days	5%	N/A	• <i>Aspergillus niger</i> (ATCC 6275)	Yes

* Although no growth was observed on any of the test carriers for this organism, carrier population controls did not achieve the minimum 4.0 log carrier count to make the test valid on any test date.

VI LABEL COMMENTS

1. The proposed label claims that the product, Valhalla RTU spray, is an effective bacterial disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 1 minute contact time:

Salmonella enterica (ATCC 10708)

These claims are **acceptable** as they are supported by the submitted data

2. The proposed label claims that the product, Valhalla RTU spray, is an effective bacterial disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 4.5 minute contact time:

Pseudomonas aeruginosa (ATCC 15442)

These claims are **acceptable** as they are supported by the submitted data.

3. The proposed label claims that the product, Valhalla RTU spray, is an effective bacterial disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 2 minute contact time:

Staphylococcus aureus (ATCC 6538)

Escherichia coli O157:H7 (ATCC 43888)

Listeria monocytogenes (ATCC 7644)

Streptococcus pyogenes (ATCC 12384)

These claims are **acceptable** as they are supported by the submitted data.

4. The proposed label claims that the product, Valhalla RTU spray, is an effective virucidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 1 minute contact time:

2009-H1N1 Influenza A virus (novel H1N1) StainA/Mexico/4108/2009, CDC #2009712192

Respiratory syncytial virus (ATCC VR-26, Strain Long)

Human Coronavirus (ATCC VR-740, Strain 229E)

These claims are **acceptable** as they are supported by the submitted data.

5. The proposed label claims that the product, Valhalla RTU spray, is an effective virucidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 2 minute contact time:

Rotavirus (ATCC VR-2018, Strain WA)

These claims are **acceptable** as they are supported by the submitted data

6. The proposed label claims that the product, Valhalla RTU spray, is an effective virucidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 5 minute contact time:

Feline Calicivirus as a surrogate virus for Norovirus

These claims are **acceptable** as they are supported by the submitted data

7. The proposed label claims that the product, Valhalla RTU spray, is an effective fungicidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 9.5 minute contact time:

Trichophyton mentagrophytes (ATCC 9533)

These claims are **acceptable** as they are supported by the submitted data

8. The proposed label claims that the product, Valhalla RTU spray, is an effective residual self-sanitizer against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 4.5 minute contact time:

Staphylococcus aureus (ATCC 6538)

These claims are **acceptable** as they are supported by the submitted data

9. The proposed label claims that the product, Valhalla RTU spray, is an effective residual self-sanitizer against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 4 minute 45 second contact time:

Enterobacter aerogenes (ATCC 13048)

These claims are **acceptable** as they are supported by the submitted data

10. The proposed label claims that the product, Valhalla RTU spray, is an effective non-food contact sanitizer against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 10 second contact time:

Enterobacter aerogenes (ATCC 13048)

Staphylococcus aureus (ATCC 6538)

These claims are **acceptable** as they are supported by the submitted data

11. The proposed label claims that the product, Valhalla RTU spray, is an effective mildew-fungistat against the following on hard, non-porous surfaces in the presence of 5% organic soil for 7 days:

Aspergillus niger (ATCC 6275)

These claims are **acceptable** as they are supported by the submitted data

12. The following changes should be made to the proposed label:

- a. In the “Directions for Use” section under “**To Sanitize**”, remove brackets (which indicate optional text) from around the following statements:
 - [non-food contact]
 - [10 seconds]
- b. In the “Directions for Use” section under “**For General Disinfection**”, remove brackets from around the following statements:
 - [Broad Spectrum]
 - [To disinfect fungi, let stand for 10 minutes]
- c. In the Directions for Use section under “**For General Disinfection**”, the disinfection contact time is 2 minutes. Claims for disinfection of other organisms with contact times shorter than 2 minutes should not appear under this heading. Instead, a statement referring the user to Table 4 for additional organisms and contact times is recommended.
- d. In the Directions for Use section under “**Residual Self Sanitizing**”, specify “non-food contact surfaces” and indicate that surfaces should be thoroughly cleaned prior to application.
- e. In the Directions for Use section under “**Shoe Sanitizer Directions**”, replace the term “prevent” with either “reduce” or “limit” in the claim “prevent tracking harmful organisms into animal areas.”
- f. In the Directions for Use section under “**[Hard Surface Mildewstat] To [Inhibit][control] Mold and Mildew**”, remove brackets from around the following statement:
 - [Hard Surface Mildewstat]
- g. Under the “**Hatcheries**,” “**Vehicles**” and “**Shoe Disinfection**” directions specify “remove heavy soil prior to treatment.”
- h. In the “**Healthcare Disinfectant Claims**” section (item #15), remove “or less” from the claim “Disinfects in 5 minutes or less.”
- i. In the “**Healthcare Disinfectant Claims**” section (item #40), add the term “hard, non-porous” to this claim.
- j. In the “**Healthcare Disinfectant Claims**” section, revise all claims of “>99.99%” to read “>99.9%”. Disinfection claims are supported by qualitative data, thus only a 99.9% kill claim is allowed.
- k. In the “**Healthcare Disinfectant Claims**” section (item #44), add the statement “when the disinfection/sanitization directions for use are followed” to this claim.
- l. In the “**General Disinfectant Claims**” section, revise all claims of “>99.99%” to read “>99.9%”.
- m. In the “**General Disinfectant Claims**” section (item #47), add the statement “when the disinfection/sanitization directions for use are followed” to this claim.

- n. In the “**Antifungal Claims**” section, revise all claims of “>99.99%” to read “>99.9%.” Also in this section indicate for use on “hard, non-porous surfaces.”
- o. In the “**Mildewstat Claims**” section, indicate a 7-day activity period (e.g., ... for up to 7 days) for all claims.
- p. In the “**Antiviral Claims**” section, correct “Influenza A Pandemic H1N1” with correct viral strain label “2009-H1N1 Influenza A virus (novel H1N1) StainA/Mexico/4108/2009, CDC #2009712192”.
- q. In the “**Antiviral Claims**” section (item #13), remove Influenza A pandemic H1N1, Respiratory Syncytial Virus, Rotavirus and Norovirus from claim “Kills 99.99%...”. The product did not achieve the 4 log reduction for these organisms.
- r. In the section “**Germ Claims**” section, remove the statement under item #25 (“In the presence of...”).
- s. In the “**Residual Claims**” section, correct the bacterial name abbreviations (i.e. *Staph* and *Enterobacter*) with the correct bacterial nomenclature (*Staphylococcus aureus* and *Enterobacter aerogenes*).
- t. In the “**Residual Claims**” section remove the following misleading claims:
- #43 “Long-lasting bacteria protection”
 - #44 “On-going bacteria protection”
 - #47-#49: all claims of “Protection”
- u. In the “**Non-Food Contact Sanitizer Claims**” section (items #20 and #21), add the term “hard, non-porous.”
- v. Note in “**Table 4 List of Organisms**” the ATCC number should be included for all organisms listed.
- w. In the “**Table 4 List of Organisms**” section, correct “Influenza A Pandemic H1N1” with correct viral strain label “2009-H1N1 Influenza A virus (novel H1N1) StainA/Mexico/4108/2009, CDC #2009712192”.
- x. Under the “**Making Claims Against Emerging Viral Pathogens**” section replace the first paragraph with the following text:

“This product meets the criteria to make the claims (identified below) against the following categories of emerging viral pathogens when the directions for use against Feline Calicivirus are used:

-Enveloped viruses

-Large non-enveloped viruses

Designated claims:”